

COVER SHEET
INITIAL ENVIRONMENTAL EXAMINATION

PROGRAM/ ACTIVITY DATA:

Program/Activity Number: AID-OAA-A-15-00070
Country/Region: Global
Program/Activity Title: ART Simplification: Optimization of Programs and Services (ART - OPS)

Implementing Partner: Right to Care

Functional Objective: Investing in People
Program Area: Health
Program Elements: HIV/AIDS

Period Covered: 10/02/2015 – 10/01/2019
LOP Amount \$237,150,751
IEE Prepared By: Clint Cavanaugh, Regional Advisors Team Lead, GH/OHA/SPER

IEE Amendment (Y/N): Yes, this is Amendment #1. The original IEE was approved on 9/1/2015.
Op Unit contact point: Clint Cavanaugh, Regional Advisors Team Lead, GH/OHA/SPER
Current Date 12/1/2017
Expiration Date Two years from date of signing or at the time of any change/amendment to the project.

ENVIRONMENTAL ACTION RECOMMENDED:

| | | | |
|------------------------|---------------|------------------------|---------------|
| Categorical Exclusion | <u> X </u> | Negative Determination | <u> X </u> |
| Positive Determination | <u> </u> | Deferral | <u> </u> |

ADDITIONAL ELEMENTS:

EMMP: | Conditions: X | Pesticides:*
*22 CFR 216.3 (b)(1) applies

SUMMARY OF FINDINGS

Under the Broad Agency Announcement for Global Health Challenges, Addendum #2, "The Simplification of Linkage to and Delivery of Antiretroviral Therapy (ART) in USAID/PEPFAR Supported Programs" was issued on May 29, 2015 and included six solutions. This Initial Environmental Examination was developed for Solutions 1-5, referred to by its project name: ART Simplification: Optimization of Programs and Services (ART - OPS), and approved on September 1, 2015. The purpose of this amendment (Amendment #1) is to update the IEE to include activities associated with the installation of prefabricated HIV clinics in the Zomba district of Malawi. Prefabricated clinics will be installed to improve HIV services by addressing a chronic lack of space in the existing facilities
The objective of ART - OPS is to support the development of sustainable, simpler, and less expensive ways of delivering successful Anti-Retroviral Therapy (ART) programs to support ambitious global targets for HIV/AIDS program within the confines increasingly constrained

budgets. Overall, there are a number of emerging technological and programmatic innovations which are potentially synergistic with one another and have great promise to facilitate ART expansion and improve outcomes. To maintain the enormous gains made in lives saved by ART, expand coverage and strengthen retention of patients on ART, ART - OPS will support solutions that will bring together promising and proven technologies, innovations, and approaches through implementation of activities framed around the following five solutions:

Description of activities (by Solution):

- 1) Alternative modes of ART delivery such as, but not limited to, community based distribution, technology assisted distribution, and other optimized drug distribution to individuals and the cost-effectiveness of these models.

Illustrative activities:

- Simplified pre-packaging of standardized drug regimens, and encouraging facilities to provide more than one-month medication to patients stable on treatment.
- Assess facility performance, patient file audits with quality assessment and improvements around documentation, particularly utilizing file audits to evaluate adherence and retention; use file audits to create lists of patients lost to follow-up and integrate with linkage and retention solutions to bring these individuals back to care.
- Facility level decentralization of pharmacy dispensing such as the provision of pre-packaged ART at the entrance to facilitate rapid drug collection for stable patients.
- Pilots of community based drug distribution and adherence through treatment clubs, support groups, home based care organizations or faith-based organizations for stable/transitioned patients; this may involve a community member collecting drugs, or a health provider delivering drugs in a community setting; comparing cost and cost-effectiveness of these different strategies.
- Public private partnerships with vendors/franchise options such as pharmacies, general medical practitioners and mobile phone airtime vendors; courier/home distribution.
- Tailored medication pick-up points in the community for particular target populations such as adolescents or commercial sex workers.
- Implement the provision of ART through private sector general practitioners and clinic and other evidenced –based models of cost-effective care tested in LMIC that have demonstrated high adherence (>92% viral load undetectable) at lower cost than in the public sector.

- 2) Innovative approaches and more effective technologies for viral load monitoring including rapid cost-effective scale up methods for programs which lead to greater efficiencies in training, sample transport, result returns, and quality assurance.

Illustrative activities:

- Implement short and medium-term technical assistance to develop cost-effective viral load monitoring strategies customized to the country's needs. These would range from broad implementation of viral load (VL) monitoring to sentinel surveillance.

- Pilot a “gatekeeper” approach to prioritize individuals who should be referred to adherence counselling before viral load testing (missed visits and/or pill count and lack of other warning signs), limiting the number of VL tests performed to conserve resources.
 - Expedite second line treatment for individuals with high risk for virologic failure from resistance in whom delays in switching may have morbidity, mortality, and public health implications (transmission of drug resistant virus).
 - Align with activities performed under other solution areas to explore the appropriate frequency of viral load monitoring in different ‘phases’ of ART (intensive, consolidation, maintenance).
 - Pilot strategies for public-private partnerships to implement and scale viral load in settings with strong private sector infrastructure.
 - Build capacity for Dried Blood Spot (DBS) sample collection to simplify sample acquisition and transportation; provide a single cut-off of VL; for example, use of a clinically significant level of 1000c/ml to define virologic failure and facilitate algorithmic decision-making.
- 3) Use of technology and innovative programmatic strategies to enable more effective linkage activities from diagnosis to treatment, adherence and retention, using community and facility collaboration models for HIV and HIV/TB co-infected individuals.

Illustrative activities:

- Household HIV Testing through “Index case trailing” or contact tracing.
- Pilot community based HCT “Index case trailing” in new settings.
- Community based adherence clubs
- MHealth solutions

- 4) Successful care and treatment approaches that directly respond to the needs of key populations as measured by increases in the number of HIV+ individuals in key population groups that are on treatment and retained in care. □

Illustrative activities:

- ‘Test and linkage KP counsellors’ to increase uptake of testing and HIV services.
- Simplification of referral pathways to competent health services through ‘test and linkage KP counsellors’, to streamline and expedite access to care. We will focus on referral pathways that are enabling for KPs and measure improvements in the cascade and cost-effectiveness of using a specialised cadre for this purpose.
- Competent clinical KP health professionals developed via an adaptable, scalable series of training modules for health workers to develop KP competency.
- Competent KP services will be established by adapting existing sexual and reproductive health/STI services to address KP needs, including dedicated KP services, men's only clinics and after-hours KP services, as required.
- Self-testing and incentivised testing pilots including measurement of cost-outcome. Deployed via existing KP networks and CBOs.
- MHealth mobile platforms to engage KP social structures and nodes to empower and strengthen networks, provide access to topical information, encourage HCT and promote utilization of trained competent clinics.
- Novel and accessible community outlets to disseminate ART as well as scarce commodities such as water-based lubricant (which could, for example, be

prescribed by a health worker) through KP-focused CBOs, at hairdressing salons, taverns, kiosks and private practitioners frequented by KPs. We will also pilot 'shared' outreach or community-based events (for example, including MSM with female sex workers in HCT events) to encourage HCT testing, treatment and linkage to care; the presence of both men and women will mitigate against participants being identified as belonging to a KP.

- Demonstration of KP-focused Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Test and Treat initiatives

- 5) Promising "Test and Treat" strategies and the cost-effectiveness of models used, as they are brought to scale globally.

Illustrative activities:

- Provide technical assistance to the Ministry of Health to assess the health cost affordability and health system implications of "Test and Treat" strategies. This includes a health economic assessment of the "investment case" of "Test and Treat" taking into account the epidemiology of HIV in-country and health costs of care to establish the feasibility of such an intervention.
- Simplification of treatment guidelines (e.g. fixed dose combinations and simple laboratory monitoring guidelines) is key to increasing and disseminating scale-up of treatment models.
- Facilitate national level policy/protocol readiness by providing technical assistance.
- Rapid expansion of treatment access including community based treatment and adherence interventions
- "QUICK WINS" to identify eligible patients for treatment: With an expansion of the treatment guidelines (from CD4+ <350 to <500; or "Test and Treat") each facility can be encouraged to undertake a file audit to contact patients currently in pre-ART care and those lost from care and support immediate initiation of ART. Within a short period of time, large numbers of patients could be brought into care.
- Innovative interventions to identify pilot projects and "Test and Treat" opportunities. Alternative treatment sites may be considered such as STI clinics, family planning clinics, antenatal clinics, and primary health clinics, including those in the private sector. Botswana successfully implemented a public-private partnership with private sector General Practitioners as providers of ART, to assist in the rapid expansion of treatment access, eventually taking those patients back into the public sector 5 years later when high levels of treatment access had been achieved. We will explore these types of partnerships in countries with a strong private healthcare infrastructure.

- 6) Installation of prefabricated HIV clinics in the Zomba district of Malawi. Prefabricated clinics will be installed to improve HIV services by addressing a chronic lack of space in the existing facilities. Activities include:

- Installation of prefabricated at 26 selected sites. The sites have been cleared but will require tree removal services at three sites.
- Installation of water supply system to provide access to potable water.

- Connection of water supply system to existing septic tanks on site. Where septic tanks were not available, 2m radius soakaways will be provided 3m away from units.
- Installation of electrical system to provide access to power.

RECOMMENDED DETERMINATIONS AND CONDITIONS

Note: Upon final approval of this IEE, these recommendations are affirmed as threshold decisions and conditions become mandatory elements of project implementation.

*Based on an assessment of project activities, it has been determined that a **Negative Determination with Conditions** is appropriate for this project. Other project activities not described in the paper will require a supplemental environmental analysis and an amendment to this IEE.*

THRESHOLD ENVIRONMENTAL DETERMINATIONS

A **Categorical Exclusion** is recommended for the activities listed below, because environmental impacts are not expected as a result of these activities (22 CFR 216.2(c)(1)). The following activities fall under the following citations from Title 22 of the Code of Federal Regulations 216.2(c)(2) as classes of activities that do not require an initial environmental examination, except to the extent provided herein:

- i. Activities involving education, training, technical assistance or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, or generation of medical waste, etc.);
- ii. Activities involving analyses, studies, academic or research workshops and meetings;
- iii. Activities involving document and information transfers;
- iv. Studies, projects or programs intended to develop the capability of recipient countries and organizations to engage in development planning.
- v. Activities involving market and user understanding, policy, and advocacy.

Pursuant to 22 CFR 216.3(a)(2), a **Negative Determination with Conditions** is recommended for any project activities that have potential for negative impact on the environment in the following categories:

- i. Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies, and reagents.
- ii. Training professional and paraprofessional health care workers in methods that result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency medical care, administration of injectables, HIV or TB testing, malaria diagnosis, etc.)
- iii. Generation, storage, management and disposal of hazardous and highly hazardous medical waste.
- iv. Activities involving the ongoing development, manufacturing, and distribution of new antiretroviral formulations.
- v. Small-scale construction and rehabilitation activities to address a chronic lack of space in existing facilities. Activities will involve the installation of prefabricated HIV clinics and connection to water supply and electrical system in each unit.
- vi. Installation of water supply systems at prefabricated HIV clinics. Prefabricated HIV clinics will be connected to a water supply system so that staff and patients have access to

potable water for washing hands and other needs. The wastewater from sinks in prefabricated clinics will be discharged into existing septic tanks. Where septic tanks are not available, 2m radius soakaways will be installed approximately 3m away from units. Latrines will not be installed at the selected sites because existing latrines have been identified and confirmed to be near and easily accessible. Thus, the wastewater will not contain excreta.

SUMMARY OF CONDITIONS

1. Environmental Management Training. The GH AOR/COR and Activity Manager(s) assigned to this program are to enroll in and successfully complete the Bureau for Global Health Environmental Management Process Training course. The course is offered through GHPOD.

2. IEE provided to Implementing Partner. The AOR will provide a copy of this IEE to the implementing partner and brief them on their environmental compliance responsibilities.

3. Pesticides or pesticide products. Any program activities conducted under this Agreement involving the procurement, use, research or disposal of pesticides or pesticide products will require a supplemental IEE or PEA amendment based on consultations with the Bureau Environmental Officer for Global Health.

4. Assurance of sub-awardee, -grantee, -contractor capacity and compliance. The implementing partner shall assure that sub-awardees, -grantees, -contractors have the capability to implement the relevant requirements of this IEE. The implementing partner shall, if appropriate, provide training to sub-awardees, -grantees, and -contractors in their environmental compliance responsibilities

5. AOR monitoring responsibilities. As required by the ADS 204, the AOR will actively monitor and evaluate whether the conditions of this IEE are being implemented effectively and whether new or unforeseen consequences arise during implementation not identified and reviewed in this IEE. If new or unforeseen consequences arise, the team will suspend the activity and initiate appropriate, further review in accordance with 22CFR216.

6. Annual compliance documentation and reporting. The IP shall complete an Environmental Mitigation and Monitoring Plan (EMMP) using the attached Environmental Mitigation and Monitoring Template (EMMT) (see EMMT Part 2 of 3: EMMP) with the submission of the annual implementation plan. The IP is responsible for preparing and submitting an annual Environmental Mitigation and Monitoring Report (EMMR), using Part 3 of the attached EMMT, and providing the report to the AOR for review and approval. The attached EMMR template will be used to document compliance with the conditions of this IEE. A checklist for the AOR to utilize in evaluating the EMMR is included as Appendix A and the EMMT is included as Appendix B.

7. Environmental Mitigation and Monitoring Report: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.

- i. The environmental monitoring report should be submitted to the AOR with the annual workplan, but no later than 45 days after the end of the fiscal year.
- ii. The EMMR will record the environmental mitigation and monitoring measures

outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.

- iii. Based on the process outlined in the Project Workplan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
- iv. The EMMR must be stored in project files.

8. Integration of compliance responsibilities in prime and sub-contracts, agreements, and grants. The AOR shall assure that the cooperative agreements document references and require compliance with the conditions set out in this IEE, as required by ADS 204.3.4(a)(6) and ADS 303.3.6(3)(e). The implementing partner shall assure that sub-contracts, agreements, and grants reference and require compliance with relevant elements of these conditions.

9. Compliance with human subject research requirements. The AOR in consultation with the BEO for the Global Health Bureau shall assure that the IP and sub-awardees demonstrate completion of all requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this agreement. The BEO for Global Health may request copies of documentation from the AOR to demonstrate compliance with applicable requirements of human subject trials. All documentation demonstrating completion of required review and approval of human subject trials must be in place prior to initiating any trials and cover the period of performance of the trial as described in the research protocol. Specifically, the implementing partner must provide a brief description of the research and the steps taken to comply with USAID requirements for the protection of human research subjects. This information must be provided to the AOR as part of the EMMP or as part of an amended EMMP.

10. New or modified activities. As part of its initial workplan, and all annual workplans thereafter, the implementing partner in collaboration with the AOR shall review all on-going and planned activities to determine if they are within the scope of this IEE. The implementing partner shall complete the screening questionnaire (Part 1 of EMMT) with the annual workplan (Appendix B).

- a. If activities outside the scope of this IEE are planned, the AOR shall assure that an amendment to this IEE addressing these activities is prepared and approved prior to implementation of any such activities.
- b. Any ongoing activities found to be outside the scope of this IEE shall be modified to comply or halted until an amendment to this IEE is submitted and approved.

11. Compliance with Host Country Requirements. Nothing in this IEE substitutes for or supersedes implementing partner, sub-awardees/-grantee/-contractor's responsibility for compliance with all applicable host country laws and regulations. The implementing partner and sub-awardee, -grantee, -contractor must comply with host country environmental regulations unless otherwise directed in writing by USAID. However, in case of conflict between host country and USAID regulations, the latter shall govern.

12. Small-Scale Construction Activities. Small-scale construction and renovation activities will involve the installation of prefabricated HIV clinics and connection to water supply and electrical system in each unit.

13. Asbestos and lead-based paint. The IP will not use construction materials containing asbestos or lead-based paint. When conducting construction or renovation activities, the IP will investigate for the presence of asbestos or lead paint prior to initiating work and will provide appropriate personal protective equipment (PPE) and a disposal process for handling the hazardous waste, if identified.

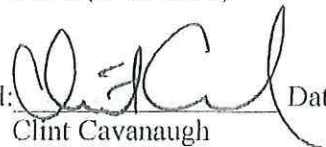
APPROVAL OF THE RECOMMENDED ENVIRONMENTAL ACTION

**ACTIVITY TITLE: ART SIMPLIFICATION: ART SIMPLIFICATION-
OPTIMIZATION OF PROGRAMS AND SERVICES (ART/OPS)**

CLEARANCE:

Agreement Officer Representative

Signed:

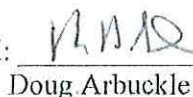

Clint Cavanaugh

Date:

12/13/17

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Signed:


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12/13/17

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Signed:


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12/20/17

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Not approved: ☐

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INITIAL ENVIRONMENTAL EXAMINATION

PROGRAM/ ACTIVITY DATA:

Program/Activity Number: AID-OAA-A-15-00070

Country/Region: Global

Program/Activity Title: ART Simplification: Optimization of Programs and Services (ART - OPS)

Implementing Partner: Right to Care

Functional Objective: Investing in People

Program Area: Health

Program Elements: HIV/AIDS

1.0 BACKGROUND AND ACTIVITY/PROGRAM DESCRIPTION

1.1 Purpose & Scope of IEE

In accordance with 22 CFR 216, this Initial Environmental Examination (IEE) reviews the reviews the reasonably foreseeable effects on the environment, including human health, of activities to be conducted under the USAID Project: ART Simplification: Optimization of Programs and Services (ART - OPS). The original IEE was approved in September 1, 2015 and is being amended to include activities associated with the installation of prefabricated HIV clinics in the Zomba district of Malawi. Prefabricated clinics will be installed to improve HIV services by addressing a chronic lack of space in the existing facilities. This amended IEE (Amendment #1) provides information on the prefabricated HIV clinics. On this basis, this IEE recommends 22 CFR 216 Threshold Decisions and attendant conditions. Upon final approval of this IEE, these recommendations are affirmed as threshold decisions and conditions become mandatory elements of project implementation.

This IEE is a critical element of a mandatory environmental review and compliance process meant to achieve environmentally sound activity design and implementation.

1.2 Cooperative Agreement Background

ART Simplification: Optimization of Programs and Services (ART - OPS) will be implemented through a Cooperative Agreement. The objective of this project is to support the development of sustainable, simpler, and less expensive ways of delivering successful Anti-Retroviral Therapy (ART) programs in order to inform the global scale-up of HIV/AIDS care and treatment programs.

The project will be implemented by a Consortium of African-based partners with strong expertise in ART service delivery implementation and research. Core competencies within the consortium include: large-scale implementation of comprehensive care and treatment programs, maternal and child health/HIV integration, large-scale community-based HIV/AIDS programs, key populations support and viral load monitoring support.

The ART - OPS is a four-year award with a ceiling of \$237,150,751.

1.3 Description of Activities

ART- OPS will support HIV/AIDS service delivery innovations in a number of areas. To maintain the enormous gains made in lives saved by ART, expand coverage and strengthen retention of patients on ART, ART - OPS will support solutions that will bring together promising and proven technologies, innovations, and approaches through implementation of pilot and proof of concept innovative activities.

The project will achieve the objective through five specific solutions:

- 1) Alternative modes of ART delivery such as, but not limited to, community based distribution, technology assisted distribution, and other optimized drug distribution to individuals and the cost-effectiveness of these models
- 2) Innovative approaches and more effective technologies for viral load monitoring including rapid cost-effective scale up methods for programs which lead to greater efficiencies in training, sample transport, result returns, and quality assurance
- 3) Use of technology and innovative programmatic strategies to enable more effective linkage activities from diagnosis to treatment, adherence and retention, using community and facility collaboration models for HIV and HIV/TB co-infected individuals
- 4) Successful care and treatment approaches that directly respond to the needs of key populations as measured by increases in the number of HIV+ individuals in key population groups that are on treatment and retained in care.
- 5) Promising "Test and Treat" strategies and the cost-effectiveness of models used, as they are brought to scale globally.
- 6) Installation of prefabricated HIV clinics in the Zomba district of Malawi. Prefabricated clinics will be installed to improve HIV services by addressing a chronic lack of space in the existing facilities. The ART & testing clinics will be of two types, namely Option 1 and Option 2.

- **Option 1** clinics will consist of 1 block which has both ART and HTS as follows:

- 1 room of 4.0m x 4.0m (for ART treatment)
- 1 room of 4.0m x 3.0m (for HTS testing)
- 1 room of 3.0m x 4.0m (for Dispensing)
- 1 room of 4.0m x 3.0m (Data Capturing)
- 1 room of 3.0m x 4.0m (for Reception)
- 1 room of 4.0m x 2.0m (for Power Supply)
- 1 veranda of 19.70m x 3.75m as waiting area

- **Option 2** clinics will consist of:

- 2 rooms of 4.0m x 4.0m (for ART treatment)
- 2 rooms of 4.0m x 3.0m (for HTS testing)
- 1 room of 3.0m x 4.0m (for Dispensing)
- 1 room of 4.0m x 3.0m (for Data Capturing)
- 1 room of 3.0m x 4.0m (for Reception)
- 1 room of 4.0m x 2.0m (for Power Supply)
- 1 veranda of 26.90m x 3.75m as waiting area

2.0 COUNTRY AND ENVIRONMENTAL INFORMATION (BASELINE INFORMATION)

2.1 Locations Affected

Activities will be informed by both core (headquarters) and field funding buy-in. However, all PEPFAR-supported countries (see Annex 1) will be eligible for support. Environmental procedures are detailed in national policies. The project is responsible for following applicable country and environmental information for identified activities that have potential to have a negative impact on the environment.

Before initiating any activities with potential environmental impact, as indicated in Section 3 below, the implementing partner must identify the sites involved, indicating whether they are clinics, hospitals, universities, or other types of facilities or locations, and whether the site and local implementers have adequate capacity to manage healthcare waste according to the requirements of the activity. The implementing partner, in consultation with the AOR, may choose to work with the host country to strengthen management of medical waste. However, the implementing partner must not contribute to or exacerbate a situation where healthcare waste management does not meet required best practices, including host country laws and regulations. It is recognized that the locations affected may not be completely known or certain at the beginning of a given project (or cooperative agreement) and that they may change over time. Therefore, if this information has not been provided to the AOR as part of an initial Environmental Monitoring and Mitigation Plan (EMMT, including Parts 1-3, Appendix B), it must be provided as part of an amended or annual EMMR.

2.2 Applicable Environmental Policies and Procedures

Evaluation, analysis, research, reviews, and meetings could occur in host-country institutions or in domestic (US) workspaces, offices, or laboratories. These activities will occur under and in line with national government environmental rules and regulations and organizational environmental policy. Most facilities are existing, so no major construction activities are planned. However, in Malawi, it is anticipated that prefabricated HIV clinics will be installed at 26 selected sites to provide better HIV services.

Before initiating any activities with potential environmental impact, as indicated in Section 3 below, the implementing partner must identify all applicable environmental laws and regulations in the country or countries where the activities will take place. The primary guide for this activity will be the World Health Organization resource, "[Safe Management of Wastes from Health-care Activities](#)" (Au2014). Additionally, the implementing partner must cite its own organization's governing regulations and guidelines that will be followed relative to these activities. Host country laws and regulations are to be followed unless they are less strict than the WHO guide for health-care waste management, which will take precedent. It is recognized that the countries involved may not be completely known or certain at the beginning of a given project (or cooperative agreement) and that they may change over time. Therefore, if this information has not been provided to the AOR as part of an initial Environmental Monitoring and Mitigation Report (EMMR, including Parts 1-3, Appendix B), it must be provided as part of an amended or annual EMMR.

Research studies involving human subjects apply the Common Federal Policy for Protection of Human Subjects in Research (commonly referred to as "the Common Rule"), as described in

ADS Chapter 200: Protection of Human Subjects in Research Supported by USAID. "The Policy sets standards for the protection of human research subjects that USAID follows when research activities supported by USAID involve human subjects. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the primary responsibility of the [IP] (p.2). As detailed in 22 CFR 225, the Common Rule describes the various functions and processes needed to ensure human subjects protection (including informed consent procedure, special protections for minors and other vulnerable populations). To ensure this organizations with a proven ethical track record of success in the provision of HIV care and treatment services and a have worked within host country national and sub-national government care and treatment programs have been selected to carry out these procedures.

For all activities involving human research subjects the implementing partner must provide a brief description of the research and the steps taken to comply with USAID requirements for the protection of human research subjects. This information must be provided to the AOR as part of an initial Environmental Monitoring and Mitigation Report (EMMR, including Parts 1-3, Appendix B), or as part of an amended or annual EMMR.

3.0 POTENTIAL ENVIRONMENTAL IMPACTS AND CONSIDERATIONS REGARDING A RECOMMENDED DETERMINATION.

Some of the project's activities do not have direct adverse environmental impacts, as they entail planning, management, desk research, data analysis, and communications activities.

Certain activities supported through the project will directly or indirectly affect the environment, or have potential to do so. Based on an analysis conducted by the AOR and USAID management team, the following activities could affect the environment:

1. **Procurement, Storage, Management and Disposal of Health Commodities:** This project will include the procurement, use and disposal of commodities including study product as well as placebo, injection equipment, laboratory supplies, and/or reagents. Any unused commodities that expire before use will be disposed of based on the World Health Organization resource, "Safe Management of Wastes from Health-care Activities" (2014), and secondarily through protocols developed by the implementing partner in accordance with USG and/or local regulations for disposal of health commodities (to be specified in the EMMP).

Pharmaceutical products have specific storage time and temperature requirements, and may expire or lose efficacy before they are used, particularly in remote areas where demand is low and/or infrequent. Pharmaceutical waste may also accumulate due to inadequacies in stock management and distribution and/or lack of a routine system of disposal. Health commodity logistics and supply chain management continue to be a priority of the program. The implementing partner will develop and implement standard operating procedures (SOPs) for the safe storage and transportation of health commodities to reduce damage or early expiration. Storage and transport considerations include, but are not limited to: storage ambient conditions, theft prevention, stock inventory and records, fire control, transport needs and availability, accident and spill response, incident reporting, and vehicle maintenance. The SOPs will be in accordance with WHO's "Safe Management of Wastes from Health-care Activities" (2014). Secondary sources may include:

- John Snow, Inc./USAID DELIVER Project in collaboration with WHO. "Guidelines for the Storage of Essential Medicines and Other Health Commodities" (2003)
- USAID DELIVER Project. "Guidelines for Warehousing Health Commodities" (Second Edition 2014). Task Order 4
- USAID DELIVER Project. "The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities" (2011)

2. **Training Professional and Paraprofessional Health Care Workers:** Improper training, handling, storage and disposal of the waste generated in healthcare facilities or activities can spread disease through several mechanisms. Transmission of disease through infectious waste is the greatest and most immediate threat from healthcare waste (HCW). If waste is not treated in a way that destroys the pathogenic organisms, dangerous quantities of microscopic disease-causing agents—viruses, bacteria, parasites or fungi—can be present in the waste. These agents can enter the body through punctures and other breaks in the skin, mucous membranes in the mouth, by being inhaled into the lungs, being swallowed, or being transmitted by a vector organism.

Healthcare workers are at greatest risk of poorly managed medical waste, but other workers are also exposed including, cleaning staff, patients, visitors, waste collectors, disposal site staff, waste pickers, substance abusers and those who knowingly or unknowingly use "recycled" contaminated syringes and needles. Although sharps pose an inherent physical hazard of cuts and punctures, the much greater threat comes from sharps that are also infectious waste. Workers handling sharps are exposed to possible HIV and hepatitis B and C viruses through pricks.

3. **Generation, Storage, Management and Disposal of Hazardous and Highly Hazardous Medical Waste:** This project will involve lab work analyzing biological samples that will also be transported from clinical sites or sample repositories and will be stored in the laboratories. Select biological samples or portions of samples may be disposed of at the laboratories after use or in the event of expiration or loss of viability. The activities that may generate waste or require disposal of waste will adhere to effective and sustainable protocols for waste management. The implementing partner will develop and implement a waste management plan (WMP) or equivalent procedures in accordance with WHO guidelines for medical waste management. Disposal considerations include, but are not limited to: waste minimization procedures, proper handling of wastes, storage of wastes (including PPE), containers and labeling, safe disposal practices and procedures, inspection protocols and frequency, and documentation requirements (e.g., waste manifests). Secondary resources may include USAID sector guidelines on healthcare waste (<http://www.usaidgems.org/Sectors/healthcareWaste.htm>). The project will comply with the World Health Organization resource, "Safe Management of Wastes from Health-care Activities" (2014), and with local regulations for waste management and disposal (to be specified in the EMMP).

Although healthcare activities provide many important benefits to communities, they can also unintentionally cause environmental impacts through poor management of the HCW. These wastes generally fall into three general categories in terms of public health risk and

recommended methods of disposal:

General healthcare waste, similar or identical to municipal waste, including materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75 – 90 percent of waste generated by healthcare facilities falls into this category, and it can be burned through low temperature incineration or taken to the landfill without any additional treatment.

Hazardous healthcare waste includes infectious waste (except sharps and waste from patients with highly infectious diseases), unusable chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.

Highly hazardous healthcare wastes, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste, such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as tuberculosis and HIV. They also include hazardous chemicals, as well as all radioactive or genotoxic wastes.

Restricting public access to unusable pharmaceuticals and healthcare commodities requires controlling both the pathways to community access and making the healthcare products unusable to the public. The public may obtain unusable pharmaceuticals that are not segregated from the municipal waste stream and disposed in uncontrolled local dumps.

4. **Activities involving the ongoing development, manufacturing, and distribution of new antiretroviral formulations:** The effects of pharmaceutical products in the environment are different from conventional pollutants. Drugs are designed to elicit specific biological effects in humans, and which may also cause biological responses in other organisms. Their main pathway into the environment is through household use and excretion, and through the disposal of unusable pharmaceuticals.

Improper disposal of unusable pharmaceutical products can have a significant impact on aquatic organisms. A wide range of pharmaceutical products has been discovered in fresh waters globally, and even in small quantities some of these compounds have the potential to cause harm to aquatic life.

5. **Small-scale construction and rehabilitation activities to address a chronic lack of space in existing facilities:** This project will involve the installation of prefabricated HIV clinics at 26 selected sites and connection to water supply and electrical system in each unit. This will require tree removal services at three site locations. Environmental impacts associated with construction activities are addressed below and environmental impacts associated with the use of potable water at the prefabricated clinics are addressed below, under the Water Supply Systems activity.

Construction activities may lead to the following adverse health and environmental impacts:

- Improper grading may result in standing water on-site, which readily becomes breeding habitat for mosquitoes and other disease vectors.
- Construction activities require a set of materials often procured locally: timber, fill, sand and gravel, bricks. Unmanaged extraction of these source materials can have adverse effects on the environment.
- Site clearing, grading, and tree removal may lead to significant soil erosion and impacts to fresh water sources from storm runoff.
- The use or removal of toxic materials such as asbestos, lead paint, formaldehyde (sometimes used in products like particle board, plywood, and insulation) are unsafe for both workers and future users of the facilities as residues can present health hazards, especially to children.
- Construction activities may present risks of physical injuries such as falls, crushes, and cuts to construction workers, as well as toxic hazards resulting from exposures cement dust, paints and solvents. Where access to a site is not well-controlled, these risks may extend to the community as well.

Operational issues may include:

- General impacts of facilities in operation: In operation, general/institutional facilities and compounds generate a set of waste streams (e.g., gray water, solid waste, etc). If improperly managed, such wastes can contaminate ground and surface water, create breeding habitat for disease vectors, etc. For example, failure to design or maintain appropriate drainage structures can result in standing water within the compound or on adjacent land.

The implementing partner should develop a design plan in accordance with international best management practices and host country laws and regulations. Construction planning should also include a site survey that adequately evaluates site conditions based on the size and complexity of the prefabricated HIV clinics.

SOPs will be implemented during the installation of prefabricated HIV clinics that are in accordance with international best management practices and host country laws and regulations. Considerations include, but are not limited to: water source protection, site security, and relevant occupational health and safety concerns. SOP guidance should include a WMP with procedures for properly disposing of non-hazardous and hazardous materials in accordance with international best management practices and host country laws and regulations. Considerations include, but are not limited to: proper handling and storage of waste, safe disposal practices and acceptable disposal locations, and use of appropriate personal protective equipment. The WMP should also provide instructions for recovering reusable materials and reduce the disposal of construction debris and wastes by recycling eligible materials such as scrap wood, scrap metal, and concrete that can safely be repurposed. Workers must be trained in all SOPs to minimize adverse health and environmental associated with small-scale construction activities.

After prefabricated HIV clinics are installed and complete, the IP will provide guidance materials and training to workers and host country organization on the proper use, operation, and maintenance of the new space.

6. **Installation of water supply systems at prefabricated HIV clinics:** Prefabricated HIV clinics will be connected to a water supply system so that staff and patients have access to

recommended methods of disposal:

General healthcare waste, similar or identical to municipal waste, including materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75 – 90 percent of waste generated by healthcare facilities falls into this category, and it can be burned through low temperature incineration or taken to the landfill without any additional treatment.

Hazardous healthcare waste includes infectious waste (except sharps and waste from patients with highly infectious diseases), unusable chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.

Highly hazardous healthcare wastes, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste, such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as tuberculosis and HIV. They also include hazardous chemicals, as well as all radioactive or genotoxic wastes.

Restricting public access to unusable pharmaceuticals and healthcare commodities requires controlling both the pathways to community access and making the healthcare products unusable to the public. The public may obtain unusable pharmaceuticals that are not segregated from the municipal waste stream and disposed in uncontrolled local dumps.

4. **Activities involving the ongoing development, manufacturing, and distribution of new antiretroviral formulations:** The effects of pharmaceutical products in the environment are different from conventional pollutants. Drugs are designed to elicit specific biological effects in humans, and which may also cause biological responses in other organisms. Their main pathway into the environment is through household use and excretion, and through the disposal of unusable pharmaceuticals.

Improper disposal of unusable pharmaceutical products can have a significant impact on aquatic organisms. A wide range of pharmaceutical products has been discovered in fresh waters globally, and even in small quantities some of these compounds have the potential to cause harm to aquatic life.

5. **Small-scale construction and rehabilitation activities to address a chronic lack of space in existing facilities:** This project will involve the installation of prefabricated HIV clinics at 26 selected sites and connection to water supply and electrical system in each unit. This will require tree removal services at three site locations. Environmental impacts associated with construction activities are addressed below and environmental impacts associated with the use of potable water at the prefabricated clinics are addressed below, under the Water Supply Systems activity.

Construction activities may lead to the following adverse health and environmental impacts:

- Improper grading may result in standing water on-site, which readily becomes breeding habitat for mosquitoes and other disease vectors.
- Construction activities require a set of materials often procured locally: timber, fill, sand and gravel, bricks. Unmanaged extraction of these source materials can have adverse effects on the environment.
- Site clearing, grading, and tree removal may lead to significant soil erosion and impacts to fresh water sources from storm runoff.
- The use or removal of toxic materials such as asbestos, lead paint, formaldehyde (sometimes used in products like particle board, plywood, and insulation) are unsafe for both workers and future users of the facilities as residues can present health hazards, especially to children.
- Construction activities may present risks of physical injuries such as falls, crushes, and cuts to construction workers, as well as toxic hazards resulting from exposures cement dust, paints and solvents. Where access to a site is not well-controlled, these risks may extend to the community as well.

Operational issues may include:

- General impacts of facilities in operation: In operation, general/institutional facilities and compounds generate a set of waste streams (e.g., gray water, solid waste, etc). If improperly managed, such wastes can contaminate ground and surface water, create breeding habitat for disease vectors, etc. For example, failure to design or maintain appropriate drainage structures can result in standing water within the compound or on adjacent land.

The implementing partner should develop a design plan in accordance with international best management practices and host country laws and regulations. Construction planning should also include a site survey that adequately evaluates site conditions based on the size and complexity of the prefabricated HIV clinics.

SOPs will be implemented during the installation of prefabricated HIV clinics that are in accordance with international best management practices and host country laws and regulations. Considerations include, but are not limited to: water source protection, site security, and relevant occupational health and safety concerns. SOP guidance should include a WMP with procedures for properly disposing of non-hazardous and hazardous materials in accordance with international best management practices and host country laws and regulations. Considerations include, but are not limited to: proper handling and storage of waste, safe disposal practices and acceptable disposal locations, and use of appropriate personal protective equipment. The WMP should also provide instructions for recovering reusable materials and reduce the disposal of construction debris and wastes by recycling eligible materials such as scrap wood, scrap metal, and concrete that can safely be repurposed. Workers must be trained in all SOPs to minimize adverse health and environmental associated with small-scale construction activities.

After prefabricated HIV clinics are installed and complete, the IP will provide guidance materials and training to workers and host country organization on the proper use, operation, and maintenance of the new space.

6. **Installation of water supply systems at prefabricated HIV clinics:** Prefabricated HIV clinics will be connected to a water supply system so that staff and patients have access to

potable water. The wastewater from sinks in prefabricated clinics will be discharged into existing septic tanks. Where septic tanks are not available, 2m radius soakaways will be installed approximately 3m away from units. Latrines will not be installed at the selected sites because existing latrines have been identified and confirmed to be near and easily accessible. Thus, the wastewater will not contain excreta.

Water supply systems may lead to the following adverse health and environmental impacts:

- Improper design and/or sizing of water supply systems can lead to the depletion or contamination of available water sources. Public health and safety concerns may also arise if the water supply systems are not appropriate for the intended use. The quantity and quality of available water sources must be adequately assessed prior to the construction of new water systems to prevent the depletion and degradation of fresh water sources and minimize adverse health and environmental impacts.
 - Improper construction of soakaways for the disposal of water from sinks (i.e. sullage) may result in standing water on-site, which readily becomes breeding habitat for mosquitoes and other disease vectors.
 - Proximity to aquatic and terrestrial ecosystems, especially sensitive species may lead to environmental impacts.
 - Proximity of drinking water systems to sanitary systems may lead to potential health and environmental impacts.
 - Water supply systems may become contaminated during construction, operation, or maintenance activities if equipment is not kept clean or debris enters the supply systems. This can lead to adverse health impacts to system users and surrounding communities from waterborne disease and illness.
-
- The implementing partner will develop a design plan based on site-specific conditions, clinic needs, and system maintenance requirements. This may involve the collection of baseline information to assess the quantity of water available at the proposed sites and water quality. Refer to WHO's "Fact Sheets on Environmental Sanitation: Introduction to Fact Sheets on Water" and USAID's "Sector Environmental Guidelines: Water Supply and Sanitation" (Partial Update: 2014, Last Full Update: 2009) for additional information. Water testing requirements and protocols should be documented in a Water Quality Assurance Plan (WQAP) and if applicable, include approach for ongoing water quality monitoring in accordance with USAID's "Standard IEE Language Establishing a Water Quality Assurance Plan (WQAP) Requirement — (Draft)" (September 26, 2014) and "USAID Sample Water Quality Assurance Plan" (2013). The implementing partner will also consult with host country regarding regulatory, permit, and monitoring requirements. Planning activities should also include a site survey to adequately evaluate site conditions based on the size and complexity of the water supply system in accordance with WHO's "Guidelines for Drinking-Water Quality, Fourth Edition" (2011). In addition, the implementing partner will refer to WHO's "Disposal of sullage and drainage" guidelines when constructing soakaways for the disposal of water from sinks (i.e. sullage).

The implementing partner is not responsible for monitoring the quality of the water supply system during operation activities, however they will at a minimum provide outreach, educational materials, and training to the clinics/users on the proper use,

operation, and maintenance of the water supply system to ensure the long-term sustainability of the system.

4.0 RECOMMENDED DETERMINATIONS AND CONDITIONS

Based on the above analysis, activities to be undertaken under ART - OPS, are recommended for a **negative determination**, subject to the following **conditions**. Upon final approval of this IEE, this recommendation is affirmed as a threshold decision and the conditions become mandatory elements of project implementation.

THRESHOLD ENVIRONMENTAL DETERMINATIONS

A **Categorical Exclusion** is recommended for the activities listed below, because environmental impacts are not expected as a result of these activities (22 CFR 216.2(c)(1)). The following activities fall under the following citations from Title 22 of the Code of Federal Regulations 216.2(c)(2) as classes of activities that do not require an initial environmental examination, except to the extent provided herein:

- i. Activities involving education, training, technical assistance or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, or generation of medical waste, etc.);
- ii. Activities involving analyses, studies, academic or research workshops and meetings;
- iii. Activities involving document and information transfers;
- iv. Studies, projects or programs intended to develop the capability of recipient countries and organizations to engage in development planning.
- v. Activities involving market and user understanding, policy, and advocacy.

Pursuant to 22 CFR 216.3(a)(2), a **Negative Determination with Conditions** is recommended for any project activities that have potential for negative impact on the environment in the following categories:

- i. Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies, and reagents.
- ii. Training professional and paraprofessional health care workers in methods that result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency medical care, administration of injectables, HIV or TB testing, malaria diagnosis, etc.)
- iii. Generation, storage, management and disposal of hazardous and highly hazardous medical waste.
- iv. Activities involving the ongoing development, manufacturing, and distribution of new antiretroviral formulations.
- v. Small-scale construction and rehabilitation activities to address a chronic lack of space in existing facilities. Activities will involve the installation of prefabricated HIV clinics and connection to water supply and electrical system in each unit.
- vi. Installation of water supply systems at prefabricated HIV clinics. Prefabricated HIV clinics will be connected to a water supply system so that staff and patients have access to potable water for washing hands and other needs. The wastewater from sinks in prefabricated clinics will be discharged into existing septic tanks. Where septic tanks are

not available, 2m radius soakaways will be installed approximately 3m away from units. No latrines will be installed at the selected sites because existing latrines have been identified and confirmed to be near and easily accessible.

5.0 SUMMARY OF CONDITIONS

1. Environmental Management Training. The GH AOR/COR and Activity Manager(s) assigned to this program are to enroll in and successfully complete the Bureau for Global Health Environmental Management Process Training course. The course is offered through GHPOD.

2. IEE provided to Implementing Partner. The AOR will provide a copy of this IEE to the implementing partner and brief them on their environmental compliance responsibilities.

3. Pesticides or pesticide products. Any program activities conducted under this Agreement involving the procurement, use, research or disposal of pesticides or pesticide products will require a supplemental IEE or PEA amendment based on consultations with the Bureau Environmental Officer for Global Health.

4. Assurance of sub-awardee, -grantee, -contractor capacity and compliance. The implementing partner shall assure that sub-awardees, -grantees, -contractors have the capability to implement the relevant requirements of this IEE. The implementing partner shall, if appropriate, provide training to sub-awardees, -grantees, and -contractors in their environmental compliance responsibilities

5. AOR monitoring responsibilities. As required by the ADS 204, the AOR will actively monitor and evaluate whether the conditions of this IEE are being implemented effectively and whether new or unforeseen consequences arise during implementation not identified and reviewed in this IEE. If new or unforeseen consequences arise, the team will suspend the activity and initiate appropriate, further review in accordance with 22CFR216.

6. Annual compliance documentation and reporting. The IP shall complete an Environmental Mitigation and Monitoring Plan (EMMP) using the attached Environmental Mitigation and Monitoring Template (EMMT) (see EMMT Part 2 of 3: EMMP) with the submission of the annual implementation plan. The IP is responsible for preparing and submitting an annual Environmental Mitigation and Monitoring Report (EMMR), using Part 3 of the attached EMMT, and providing the report to the AOR for review and approval. The attached EMMR template will be used to document compliance with the conditions of this IEE. A checklist for the AOR to utilize in evaluating the EMMR is included as Appendix A and the EMMT is included as Appendix B.

7. Environmental Mitigation and Monitoring Report: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.

- i. The environmental monitoring report should be submitted to the AOR with the annual workplan, but no later than 45 days after the end of the fiscal year.
- ii. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.
- iii. Based on the process outlined in the Project Workplan, the implementing

partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.

- iv. The EMMR must be stored in project files.

8. Integration of compliance responsibilities in prime and sub-contracts, agreements, and grants. The AOR shall assure that the cooperative agreements document references and require compliance with the conditions set out in this IEE, as required by ADS 204.3.4(a)(6) and ADS 303.3.6(3)(e). The implementing partner shall assure that sub-contracts, agreements, and grants reference and require compliance with relevant elements of these conditions.

9. Compliance with human subject research requirements. The AOR in consultation with the BEO for the Global Health Bureau shall assure that the IP and sub-awardees demonstrate completion of all requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this agreement. The BEO for Global Health may request copies of documentation from the AOR to demonstrate compliance with applicable requirements of human subject trials. All documentation demonstrating completion of required review and approval of human subject trials must be in place prior to initiating any trials and cover the period of performance of the trial as described in the research protocol. Specifically, the implementing partner must provide a brief description of the research and the steps taken to comply with USAID requirements for the protection of human research subjects. This information must be provided to the AOR as part of the EMMP or as part of an amended EMMP.

10. New or modified activities. As part of its initial workplan, and all annual workplans thereafter, the implementing partner in collaboration with the AOR shall review all on-going and planned activities to determine if they are within the scope of this IEE. The implementing partner shall complete the screening questionnaire (Part 1 of EMMT) with the annual workplan (Appendix B).

- a. If activities outside the scope of this IEE are planned, the AOR shall assure that an amendment to this IEE addressing these activities is prepared and approved prior to implementation of any such activities.
- b. Any ongoing activities found to be outside the scope of this IEE shall be modified to comply or halted until an amendment to this IEE is submitted and approved.

11. Compliance with Host Country Requirements. Nothing in this IEE substitutes for or supersedes implementing partner, sub-awardees/-grantee/-contractor's responsibility for compliance with all applicable host country laws and regulations. The implementing partner and sub-awardee, -grantee, -contractor must comply with host country environmental regulations unless otherwise directed in writing by USAID. However, in case of conflict between host country and USAID regulations, the latter shall govern.

12. Small-Scale Construction Activities. Small-scale construction and renovation activities will involve the installation of prefabricated HIV clinics and connection to water supply and electrical system in each unit.

13. Asbestos and lead-based paint. The IP will not use construction materials containing asbestos or lead-based paint. When conducting construction or renovation activities, the IP will investigate for the presence of asbestos or lead paint prior to initiating work and will provide appropriate personal protective equipment (PPE) and a disposal process for handling the hazardous waste, if identified.

Annex 1. Healthcare Waste Management Minimal Program Checklist and Action Plan for Training Materials/Programs

| <i>Elements/Actions</i> | <i>In Place?</i> | <i>Next Steps to be done</i> | | |
|--|------------------|------------------------------|----------------|----------------|
| | | <i>What</i> | <i>By Whom</i> | <i>By When</i> |
| <i>Written plans and procedures</i> | | | | |
| 1. <i>A written waste management plan</i> Describing all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required. | | | | |
| 2. <i>Internal rules for generation, handling, storage, treatment, and disposal of healthcare waste.</i> | | | | |
| 3. <i>Clearly assigned staff responsibilities that cover all steps in the waste management process.</i> | | | | |
| 4. <i>Staff waste handling training curricula or a list of topics covered.</i> | | | | |
| 5. <i>Waste minimization, reuse, and recycling procedures.</i> | | | | |
| <i>Staff Training, Practices, and Protection*</i> | | | | |
| 6. <i>Staff trained in safe handling, storage, treatment, and disposal.</i> Does staff exhibit good hygiene, safe sharps handling, proper use of protective clothing, proper packaging and labeling of waste, and safe storage of waste? Does staff know the correct responses for spills, injury, and exposure? | | | | |
| 7. <i>Protective clothing available for workers who move and treat collected infectious waste</i> such as surgical masks and gloves, aprons, and boots. | | | | |
| 8. <i>Good hygiene practices.</i> Are soap and, ideally, warm water readily available workers to use and can workers be observed regularly washing. | | | | |

Appendix A: Tools for USAID Agreement Officer's
Representative to Evaluate the EMMP

| | | | | |
|---|--|--|--|--|
| 9. <i>Workers vaccinated for against viral hepatitis B, tetanus infections, and other endemic infections for which vaccines are available.</i> | | | | |
| <i>Handling and Storage Practices</i> | | | | |
| 10. <i>Temporary storage containers and designated storage locations.</i> | | | | |
| <ul style="list-style-type: none"> Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes? | | | | |
| 11. <i>Minimization, reuse, and recycling procedures.</i> | | | | |
| <ul style="list-style-type: none"> Does the facility have good inventory practices for chemicals and pharmaceuticals, i.e.: <ul style="list-style-type: none"> use the oldest batch first; open new containers only after the last one is empty; procedures to prevent products from being thrown out during routine cleaning? | | | | |
| 12. <i>A waste segregation system.</i> | | | | |
| <ul style="list-style-type: none"> Is general waste separated from infectious/hazardous waste? Is sharp waste (needles, broken glass, etc.) collected in separate puncture-proof containers? Are other levels of segregation being applied (e.g. hazardous liquids, chemicals and pharmaceuticals, PVC plastic, and materials containing heavy metals (these are valuable, but less essential))? | | | | |
| 13. <i>Temporary storage containers and designated storage locations.</i> | | | | |
| <ul style="list-style-type: none"> Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes? Is the location distant from patients or food? | | | | |
| <i>Treatment Practices</i> | | | | |
| 14. <i>Frequent removal and treatment of waste</i> | | | | |
| <ul style="list-style-type: none"> Are wastes collected daily? | | | | |

| | | | | |
|--|--|--|--|--|
| <ul style="list-style-type: none"> • Are wastes treated with a frequency appropriate to the climate and season? <ul style="list-style-type: none"> ◦ Warm season in warm climates within 24 hrs ◦ In the cool season in warm climates within 48 hrs ◦ In the warm season in temperate climates within 48 hrs | | | | |
| <p>15. <i>Treatment mechanisms for hazardous and highly hazardous waste. (The most important function of treatment is disinfection).</i></p> <ul style="list-style-type: none"> ▪ Are wastes being burned in the open air, in a drum or brick incinerator, or a single-chamber incinerator? • If not are they being buried safely (in a pit with an impermeable plastic or clay lining)? • Is the final disposal site (usually a pit) surrounded by fencing or other materials and in view of the facility to prevent accidental injury or scavenging of syringes and other medical supplies? • Is the disposal site not near a natural water shelf? | | | | |
| 16. If the waste is transported off-site, are precautions taken to ensure that it is transported and disposed of safely? | | | | |

* Training should be conducted before starting activity implementation

For more detailed checklists and guidance consult: *Safe management of wastes from health-care activities*, edited by A. Prüss, E. Girault and P. Rushbrook. Geneva, WHO, 1999, http://www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm. English

Appendix B: Environmental Mitigation and Monitoring Template (EMMT)

FROM RESEARCH TO ROLL-OUT: ART Simplification-Optimization of Programs and Services
(ART/OPS)

Part 1 of 3: Environmental Screening Form

| | |
|--|---|
| Project Name: _____ | Original IEE File #/DCN: _____ |
| Name of Prime Implementing Organization: _____ | Date of Screening: _____ |
| Name of Sub-awardee Organization (if this EMMT is for a sub): _____ | Funding Period for this award: FY _____ - FY _____ |
| Geographic location of USAID-funded activities (Province, District): _____ | Current FY Resource Levels: FY _____ |
| This report prepared by: Name: _____ Date: _____ | Date of Previous EMMT for this organization (if any): _____ |

Indicate which activities your organization is implementing.

| Key Elements of Program/Activities Implemented | | Yes | No |
|--|---|-----|----|
| 1 | Education, Technical Assistance, or Training Includes: strategic planning, data analysis, technical consultation, surveys, knowledge and information transfer, meetings, technical material development, outreach programs, and training services. | | |
| 2 | Research and Development Includes: health-related research and development activities aimed at advancing knowledge and technology, including research and evaluation, monitoring and surveillance, programs, pilot studies, case studies, and assessments. | | |
| 3 | Public Health Commodities Includes: procurement, storage, transportation, distribution, and disposal of public health commodities, including pharmaceuticals, nutritional supplements, chemicals (e.g., disinfectants, solvents, laboratory reagents, etc.), medical supplies, and family planning commodities (e.g., contraceptives, condoms, etc.). | | |

| | | | |
|---|---|--|--|
| 4 | <p>Small-Scale Construction or Rehabilitation</p> <p>Includes: hospitals, clinics, laboratories, voluntary and counseling testing centers, or training centers. Total surface area of the disturbed environment is under 10,000 square feet and less than \$200,000 total cost.</p> | | |
| 5 | <p>Small-Scale Water and Sanitation</p> <p>Includes: pond and spring improvements and installation of hand-dug wells, individual or community latrines, hand-washing stations, and small-scale septic and leach field systems.</p> | | |
| 6 | <p>Nutrition</p> <p>Includes: small-scale food production, procurement and distribution of supplements, preventing undernutrition, providing nutritional care and support, and improving nutritional outcomes in programs.</p> | | |
| 7 | <p>Vector Control</p> <p>Includes: procurement, distribution, or use of pesticide products such as insecticide-treated bednets, larviciding agents, and fumigants.</p> <p>NOTE: USAID uses USEPA's definition of pesticides, which includes "any substance intended for: preventing, destroying, repelling, or mitigating any pest. This includes herbicides, fungicides, plant regulators, and desiccants."</p> | | |
| 8 | <p>Emergency Response</p> <p>Includes: coordination with outside organizations and technical experts, deployment of resources and response teams, and development of technical materials.</p> | | |

DESCRIPTION OF ACTIVITIES:

Provide a description of activities with sufficient details to understand the scope and scale of the interventions. The EMMP should reference the governing IEE (GH- or country-level).

Project Name: _____

IEE File #/DCN: _____

Part 2 of 3: Environmental Mitigation and Monitoring Plan (EMMP)

| Category of Activity from Section 2.6 of the ____ IEE | Describe specific environmental impacts of your organization's activities (based on analysis in Section 2.5 of the ____ IEE) | Description of Mitigation Measures for these activities as required in Section 2.6 of the ____ IEE | Who is responsible for monitoring? | Monitoring Indicator | Monitoring Method | Frequency of Monitoring |
|---|--|--|------------------------------------|----------------------|-------------------|-------------------------|
| 1. Education, Technical Assistance, Training | | | | | | |
| 2. Research and Development | | | | | | |
| 3. Public Health Commodities | | | | | | |
| 4. Small-Scale Construction | | | | | | |
| 5. Small-Scale Water and Sanitation | | | | | | |
| 6. Nutrition | | | | | | |
| 7. Vector Control | | | | | | |
| 8. Emergency Response | | | | | | |

Prepared by:

Signature
Name and Title

Date: _____

Reviewed and Approved by:

Signature

Date: _____

Agreement Officer's Representative/Contracting Officer's Representative

Concur:

Signature

Date: _____

GH Bureau Environmental Officer

| | | |
|---------------------|-----------------------|------------------------|
| Project Name: _____ | IEE File #/DCN: _____ | EMMP File #/DCN: _____ |
|---------------------|-----------------------|------------------------|

Part 3 of 3: Environmental Mitigation and Monitoring Report (EMMR)

| List each Mitigation Measure from column 3 in the EMMP (EMMT Part 2 of 3) | Status of Mitigation Measures | List any outstanding issues relating to required conditions | Remarks |
|---|-------------------------------|---|---------|
| 1. Education, Technical Assistance, Training | | | |
| 2. Research and Development | | | |
| 3. Public Health Commodities | | | |
| 4. Small-Scale Construction | | | |
| 5. Small-Scale Water and Sanitation | | | |
| 6. Nutrition | | | |
| 7. Vector Control | | | |
| 8. Emergency Response | | | |

Prepared by:

Signature _____
Name and Title _____

Date: _____

ANNEX 1
PEPFAR SUPPORTED COUNTRIES

Angola
Asia Regional
(China, Laos, and Thailand)
Botswana
Burma
Cambodia
Cameroon
Caribbean Regional
(Antigua and Barbuda, Bahamas, Barbados,
Dominica, Grenada, Jamaica, St. Kitts and
Nevis, St. Lucia, St. Vincent, Suriname, and
Trinidad and Tobago)
Central America Regional
(Belize, Costa Rica, El Salvador, Guatemala,
Honduras, Nicaragua, and Panama)
Central Asia Regional
(Kazakhstan, Kyrgyz Republic, Tajikistan,
Turkmenistan, and Uzbekistan)
Côte d'Ivoire
Democratic Republic of the Congo
Dominican Republic

Ethiopia
Ghana
Guyana
Haiti
India
Indonesia
Kenya
Lesotho
Malawi
Mozambique
Namibia
Nigeria
Papua New Guinea
Rwanda
South Africa
South Sudan
Swaziland
Tanzania
Uganda
Ukraine
Vietnam
Zambia
Zimbabwe